STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE COMMISSIONER OF HEALTH

In the Matter of Good Shepherd in Sauk Rapids; Survey Exit Date September 18, 2009

**RECOMMENDED DECISION**

The above matter was the subject of an independent informal dispute resolution (IIDR) conducted by Administrative Law Judge Beverly Jones Heydinger on February 18, 2010. The OAH record closed at the conclusion of the conference that day.

Marci Martinson, IIDR Coordinator, Licensing and Certification Program, appeared on behalf of the Department of Health's Division of Compliance Monitoring (Department). Mary Cahill, Planner Principal with the Division of Compliance Monitoring, also participated in the conference. Susan M. Schaffer, Attorney at Law, appeared on behalf of Good Shepherd Lutheran Home in Sauk Rapids (Facility). The following Facility representatives also participated in the conference: Bruce Glanzer, President and C.E.O; Teri Roske, Corporate Secretary; Chris Jones, Vice President of Residential Services and Director of Nursing; Kumaree Johnson, Assistant Director of Nursing; Beverly Wiebe, Registered Nurse and Unit Manager, and Dr. Charles Pogemiller, Medical Director and attending physician.

## NOTICE

In accordance with Minn. Stat. § 144A.10, subd.16(d)(6), this recommended decision is not binding on the Commissioner of Health. As set forth in Department of Health Information Bulletin 04-07, the Commissioner must mail a final decision to the Facility indicating whether or not the Commissioner accepts or rejects the recommended decision of the Administrative Law Judge within 10 calendar days of receipt of this recommended decision.

Based upon the exhibits submitted and the arguments made and for the reasons set out in the Memorandum that follows, the Administrative Law Judge makes the following:

## RECOMMENDED DECISION

It is hereby recommended:

Tag F 314 is not supported by the facts and should be deleted.

Dated: March 3, 2010.

s/Beverly Jones Heydinger
Beverly Jones Heydinger
Administrative Law Judge

Reported: Digitally recorded (no transcript prepared).

## MEMORANDUM

### Introduction

In September 2009, a surveyor for the Department of Health and Centers for Medicare and Medicaid Services (CMS) conducted a standard survey at the Facility. On or about October 5, 2009, the surveyor issued a Summary Statement of Deficiencies to the Facility that included a citation for a violation of Tag F 314 (quality of care, mental and psychosocial functioning). The violation was cited as a G-level deficiency, based upon the surveyor's conclusion that the deficiency was isolated in scope with a severity level of actual harm that is not immediate jeopardy.[1]

The Facility disputes this citation and asserts that it should be deleted; or in the alternative, that the severity level should be reduced from G-level (actual harm) to D-level (no actual harm with potential for more than minimal harm that is not immediate jeopardy).

At the time of the survey, Resident #10 (Resident) was an 84-year-old woman with diagnoses of multiple sclerosis, neurogenic bladder, diabetes Type II, constipation, essential hypertension, brain syndrome with pre-senile brain disease, and osteoporosis. She had resided at the Facility for approximately 22 years.[2] The Respondent was identified at risk for a reoccurring "Stage II" pressure ulcer on her left buttocks. Stage II is "a partial thickness loss of skin layers that presents clinically as an abrasion, blister, scab or shallow crater."

The Department issued a deficiency for the Resident's care, Tag F314, finding a violation of 24 C.F.R. § 428.25 (c), which addresses pressure sores, otherwise referred to in the documentation as pressure ulcers. The Statement of Deficiencies stated that:

> Based on observation, interview and record review the facility failed to ensure that 1 of 1 resident #10 with an identified pressure ulcer (PU) received the necessary care and treatment to prevent pressure ulcers from redeveloping which resulted in actual harm. Findings include:

[1] Ex. E.
[2] EX. 2.

> Resident #10 was identified at risk for reoccurring stage II (a partial thickness loss of skin layers that presents clinically as an abrasion, blister, scab or shall crater) pressure ulcer on her left buttocks. The resident lacked a comprehensive pressure ulcer assessment and did not receive the necessary care and treatment to prevent the reoccurrence of the pressure ulcer on her left buttocks which reoccurred on 9-17-09 resulting in actual harm.[3]

The Facility asserted that its staff did provide the Resident with a comprehensive assessment, appropriate treatment and services for her pressure ulcer, and that the reoccurrence of a pressure ulcer was unavoidable and not related to a lack of assessment or to a failure to provide necessary care and treatment. Moreover, it asserted that the Resident did not sustain actual harm.[4]

**Factual Background**

Observations of the Surveyor

The surveyor's notes, Exhibit F-8 through F-13, report that on September 17, 2009, at 9:30 a.m., the surveyor observed that the Resident was sitting in her wheelchair in her room with the sling from the Hoyer Lift under her body. At 10:15 a.m., when questioned by the surveyor, a nursing assistant stated that she had changed the Resident's incontinent brief at around 7:00 a.m. when the Resident got up for the morning. Since that time, the nursing assistant had repositioned the Resident by moving her from side to side in the wheelchair, and checked whether the Resident's incontinent pad was wet and needed changing by having her lean back and forth, with her dress pulled up. At around 10:15 a.m. the Resident was wheeled to Bible study.

At 1:00 p.m., the surveyor again observed the Resident sitting in her room in her wheelchair. The Resident stated that she had not been changed nor had she laid down since rising that morning, and that she was tired and wet. At approximately 1:15 p.m., the Resident was put to bed. A nursing assistant stated that she had changed the incontinent pad and it was approximately 75 percent wet. The surveyor observed that the Resident's left buttock area was red, indented and creased from the incontinent product, and there was an open area that the surveyor estimated was approximately 1 to 1.25 centimeters is size, surrounded by a "beet red" and shiny area of about one inch. The nursing assistant stated to the surveyor that the area "looks better." The surveyor determined that the Resident had a recurring Stage II pressure ulcer.

The surveyor reviewed the physician's orders for the Resident, dated June 26, 2009, which stated that the Resident's incontinent product should be changed every two hours, and that she should be repositioned frequently. The care plan, dated June 22, 2009, stated that the Resident was at risk for skin breakdown due to incontinence, that her skin should be checked each week with baths and daily when dressed, and that the nurse was to be informed of any changes to the skin. The care plan dated August 25, 2009, stated that the resident should be turned or repositioned every two hours.

[3] Ex. F-10.
[4] See Ex. C-4

Based on her observations and the nursing assistants' statements, the surveyor concluded that the Resident's care plan had not been updated to reflect that she had a pressure ulcer or that the pressure ulcer was being monitored or evaluated. The surveyor believed that her conclusion was further supported by the R.N. Manager's statement to the surveyor on September 18, 2009, that she had not been aware of the Resident's pressure ulcer until staff brought it to her attention on September 17, 2009. The surveyor also concluded that the resident had not been toileted or repositioned for over six hours, from approximately 7:00 a.m. to 1:10 p.m.

The surveyor also reviewed the "Skin Condition/Wound Progression" notes in the Resident's medical record from July 1, 2008, through September 21, 2009. It showed recurring pressure ulcers and healing. Several weekly "General Nurses Observations" were provided, including one for September 3, 2009, that did not note any open areas. Reports for each week were requested but not provided to the surveyor. Other reports in the Resident's file identified that she required repositioning every two hours that she was in the wheelchair. The surveyor did not find a Braden Scale, which measures a resident's risk for pressure ulcers. A "Pressure Ulcer Resident Assessment Protocol (RAP)," dated July 28, 2009, identified that the resident was at high risk for skin breakdown, and that the skin was intact at that time, with the use of a pressure-relieving mattress, turning and repositioning.

Based on the observations and review of patient records, the surveyor concluded that the Resident had an identified risk of pressure ulcers, that she did not have a comprehensive pressure ulcer assessment, that the Resident had not had been repositioned or had her incontinent pad changed every two hours as directed by the care plan, and that the Resident had not received the necessary care and treatment to prevent the reoccurrence of a pressure ulcer. Accordingly, the Department issued Tag F314.

Setting the Level of Severity and Scope

The Department issued Tag F314 at a Severity Level of 3, affecting the resident's ability to maintain or reach her highest practicable physical well-being, and a Scope Level III, an isolated instance.

Severity Level 3 is defined as:

> Noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequence to the resident.

The Investigative Protocol for pressure ulcers includes direction for determining the severity level of the noncompliance. The guidance for Severity Level 3 includes noncompliance that results in actual harm, including clinical compromise, decline, or the resident's ability to maintain or reach her highest practicable well-being. Examples of

negative outcomes include the development of avoidable Stage III pressure ulcers, the development of recurrent or multiple avoidable Stage II pressure ulcers, and failure to implement a comprehensive care plan addressing the resident who is susceptible to pressure ulcers. The guidance states that there is a failure to implement a comprehensive plan if:

> As a result of a facility's failure to implement a portion of an existing plan related to pressure ulcer care, such as failure to provide for pressure redistribution, or inappropriate treatment/dressing changes, a wound increased in size or failed to progress towards healing as anticipated, or the resident experienced untreated pain.[5]

For Scope, Level III is defined as isolated if:

> One or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations.

In determining the scope, the Department evaluates the cause of the deficiency. If the facility does not have an adequate system or policy in place and its failure to do so may affect a large number of residents in the facility, the deficient practice is considered "widespread." If there is an adequate system or policy in place but it is inadequately implemented, or if the system or policy is inadequate and could have a negative impact on a segment of the facility's population, it is considered a "pattern." When the deficiency will likely affect one or only a few residents, it is considered "isolated."

The Department also applies a "Psychosocial Outcome Severity Guide" to help the surveyors determine the psychosocial outcome from the identified F Tag. The applicable matrix is printed at Exhibit C-4. The Department assigned a level of "G," which reflects the Department's determination that this was an isolated incident, and that there was actual harm to the resident but the resident was not in immediate jeopardy.

<u>The Facility's Response</u>

The Facility contends that the Resident's records reflect a comprehensive assessment of the Resident's condition. It completed a Minimum Data Set on July 28, 2009. Its Section M, Skin Condition, documented that the Resident had no ulcers and none resolved in the most recent 90 days.[6] It reflected several skin treatments in use at that time, including pressure relieving devices for bed and chair, repositioning program and preventative or protective skin care. Areas for further assessment included, among others, urinary continence and indwelling catheter, and pressure ulcers.[7] A Resident Assessment Protocol (RAP) was completed for these areas. The RAP Summary for

[5] Ex. G-35 – G-36.
[6] On April 12 and 13, 2009, a pressure ulcer was documented. There were no subsequent updates concerning that pressure ulcer noted on the Skin Condition/Wound Progression, Ex. 9, so it is not clear if there was a pressure ulcer present within the 90 days prior to July 28, 2009.
[7] Ex. 3 at 6 and 9.

Urinary Continence and Indwelling Catheter identified the Resident's risk of skin breakdown, odor and infection.[8] Similarly, the RAP for Pressure Ulcers stated that the Resident had a history of skin breakdown, that it was clear and intact at that time with the use of a pressure relieving mattress, turning and repositioning, and that the Resident was at high risk of skin breakdown.[9]

A Skin Risk Assessment and Care Planning Tool, dated July 23, 2009, was completed when the Resident's catheter was removed and could not be replaced. It reflected the Resident's incontinence and risk of pressure ulcers.[10] The Facility also completed Tissue Tolerance Testing at that time, indicating that the Resident could tolerate placement in a chair with repositioning every two hours.[11]

The Facility was unable to provide the surveyor with the "Braden Scale for Predicting Pressure Sore Risk" (Braden Scale) completed in July 2009, because of a computer error, but it did have copies completed in January and April 2009.[12] The Skin Condition/Wound Progress included notes entered into the Resident's medical record between July 2, 2008, and September 21, 2009. The Facility's Skin Policy stated that the plan of care should be reviewed weekly when there was a skin breakdown.[13]

The Facility also demonstrated that it had taken many steps to address the Resident's risk. The R.N. Manager pointed out that the Resident's specialized wheelchair is easily tilted[14] and is fitted with a pad that is shaped to the Resident and contoured to take the pressure off of bony areas.[15] The pad used with the Hoyer lift remains in the Resident's wheelchair but the Resident does not sit on it.[16] The Resident wears a highly-absorbent Covidien incontinent brief.[17]

The portion of the Resident's Care Plan for skin care dated June 22, 2009, was in effect for the Resident on September 17, 2009. It directed staff to check her skin each week with baths and daily when dressing, use the pressure relieving devices on her bed and wheelchair, keep her skin dry, follow the physician's directions for skin care, follow the Facility's wound protocol, and notify the unit manager and physician if the Resident's skin condition changed or wounds were not improving over a two-week period.[18]

The R.N. Unit Manager interviewed the nursing assistants on duty who confirmed that they had checked the Resident when she awoke at 7:00 a.m., at 9:10 a.m., 11:10 a.m., and 1:10 p.m., as required by the care plan.[19] The Unit Manager claimed that the

[8] Ex. 4 at 6 of 18, 11/9/09.
[9] Ex. 4 at 16 of 18, 11/9/09.
[10] Ex. 5.
[11] Ex. 7.
[12] Test. of Jones.
[13] Ex. 10.
[14] Exs. 20, 21.
[15] Exs. 22, 23, 34.
[16] Ex. 16.
[17] Ex. 17.
[18] Ex. 18.
[19] Exs. 11, 12, 13.

surveyor had misunderstood the statements made by the nursing assistants about when the Resident had been checked and her incontinent pad changed. She acknowledged that the Resident did have a pressure ulcer on September 17, 2009, but that it was approximately 0.7 centimeters in diameter, with a surrounding area of redness of approximately 6 centimeters, and that it was "new," which was obvious from its small size. Had the Resident had a pressure sore for a day or more, it would have been larger.

The Resident's physician opined that, in light of the Resident's overall physical condition, including poor skin quality, lack of muscle and incontinence, pressure sores will occur, despite the best efforts of the staff to prevent them. He pointed out that the staff's excellent efforts were borne out by the absence of pressure sores in the three months following removal of the Resident's catheter. He noted that, because of her condition, the Resident was susceptible to more serious Stage III or IV pressure sores, which the Facility's care had prevented. The Director of Nursing concurred that, in light of the Resident's condition, only close attention to skin care prevented frequent reoccurrence of the ulcers and allowed those that occurred to heal. She pointed out that the Facility's rate of pressure sores for high-risk long-term residents is six percent, below the Minnesota average of seven percent and the national average of eleven percent. Its rate for short-term residents is also lower than the Minnesota and national averages.[20]

**Discussion**

Tag F 314 is based upon an alleged violation of 42 C.F.R. § 483.25(c). Section 483.25(c) requires that a facility must ensure that

> (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
>
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

In 2004, the Centers for Medicare and Medicaid Services (CMS) issued interpretive guidelines for pressure ulcers. The Department, in conjunction with provider organizations, provided training for providers throughout the state to assure that all providers had the new guidelines addressing pressure sores and to improve care for nursing home residents in Minnesota.[21]

The Department maintained that Tag F314 was warranted because the Facility did not do a comprehensive assessment of the Resident for pressure-ulcer risk after her catheter was removed, that the Facility did not implement the Resident's care plan, that the Facility failed to monitor a pressure ulcer after it developed, or revise the care plan at that time, that the Resident was not repositioned every two hours according to her

[20] Ex. 33.
[21] Department IIDR Exhibit List and Summary at 2.

care plan, and that the Resident's incontinence was improperly monitored for six hours on September 17, 2009.

The ALJ is not persuaded that the deficiency was warranted. In order to support Tag F314, the Department must demonstrate that, taking into account the Resident's clinical condition, the pressure sore was avoidable. There was ample evidence that pressure sores were unavoidable for this Resident. In addition, the Resident had a comprehensive assessment in the summer of 2009, after her catheter was removed. The Facility was well-aware of the Resident's risk of developing pressure ulcers and had taken several steps to reduce the risk. Despite the Resident's fragile condition, pressure sores were largely prevented, and the few that occurred were treated and resolved before progressing to Stage III or IV. As the Resident's treating physician stated, given the Resident's medical condition, pressure ulcers were unavoidable, and the monitoring and care provided by the Facility prevented them from worsening.

To support Tag F314, the Department must also demonstrate that the Resident failed to receive necessary treatment and services to promote healing, prevent infection and prevent new sores from developing. In this instance, the tag was based on the Facility's failure to prevent new sores from developing.

There is conflicting evidence about whether the Resident's care plan was followed. The statements of the nursing assistants could have been reasonably interpreted to imply that the pressure sore was present prior to September 17, 2009. However, their statements can also be explained by their familiarity with the Resident's poor skin condition and prior history of pressure ulcers. It is unlikely that the pressure sore had been present and untreated for any length of time because of its small size and stage, and, when measured, it was smaller than the surveyor had surmised from observation. The Facility acknowledged that there was delay in reporting to the Unit Manager and has taken steps to improve prompt reporting.[22]

The surveyor concluded that the Resident was not repositioned, as required by the care plan. Although the Resident remained out of bed for about six hours, she was repositioned in her specially designed wheelchair and pad. The Resident's position could be changed easily and the Resident's daughter and the staff were well aware of the need to reposition. The surveyor could not have continuously observed the Resident throughout the six hours. The Facility demonstrated that participation in certain activities was important to the Resident, and that repositioning her in her wheelchair would relieve pressure to susceptible areas. The surveyor's conclusion was incorrect because repositioning in the wheelchair was consistent with the Resident's care plan.

There is conflicting evidence of whether the Resident's incontinent pad was changed at any time between approximately 7:00 a.m. and 1:00 p.m. The Facility does not dispute that the incontinence pad was checked but not changed at around 9:00 a.m., as noted by the surveyor.[23] However, the Facility contends that the incontinent

[22] Ex. F-9.
[23] Ex. 11.

pad was changed at around 11:00 a.m. It relies on the Resident's chart and the Unit Manager's interview with the nursing assistants to support that claim.[24]

The notation in the chart is not particularly persuasive since the same notation would also apply to 9:00 a.m., when it is undisputed that the incontinent pad was checked but not changed. The surveyor noted that the nursing assistants helping the Resident at around 1:00 were not aware of when the Resident had last been changed. It is not clear what other efforts the surveyor made to determine if the Resident had been changed at around 11:00. The Resident's statement that she had not been in bed since she was dressed in the morning was consistent with the statement of the nursing assistants that they had not put her to bed and had changed her pad while she was in the wheelchair.[25] Thus, the only real dispute is whether the Resident was changed at around 11:00. The fact that the Resident's pad was wet at 1:00 does not demonstrate that she was not changed at 11:00. Also, the nursing assistants interviewed by the Unit Manager were not the same nursing assistants who told the surveyor that they were uncertain when the Resident had last been changed. One of the nursing assistants questioned by the surveyor was a male; the two persons interviewed by the Unit Manager were female.

Thus, there is conflicting evidence of whether the Resident was changed at 11:00, but even if the Resident was not changed, it was the only deviation from the care plan.

The Department acknowledged that the Resident may have chosen to attend Bible study rather than lie down, but it asserted that there was no evidence that the Resident was informed of the risk of remaining in her wheelchair to attend the activity, that she knew that she had a pressure ulcer or that she was offered the opportunity to lie down prior to or after the chosen activity.

The R.N. Unit Manager explained that the Resident's daughter, who lives in an apartment adjacent to the Facility, was with her mother on September 17, 2009. The daughter understands the Resident's propensity for developing pressure ulcers and routinely adjusts the angle of her mother's wheelchair two or three times each hour. On September 17, 2009, the daughter accompanied her mother to Bible study, repositioned her, and then accompanied her mother to "News and Views," another activity at the Facility. The R.N. Unit Manager noted that the Resident's family is well-aware of her skin condition but is equally concerned about her quality of life.[26]

Thus, the evidence taken as a whole does not support Tag F314. As the witnesses for the Facility credibly testified, they are very attentive to the Resident, well aware of her tendency to develop pressure ulcers, those tendencies are covered in her assessment, and the care plan includes the appropriate steps to minimize their reoccurrence. The Department failed to demonstrate any clear deviation from the care plan on September 17, 2009, and if there was one, that it had any significant effect on the Resident's well-being.

[24] Exs. 11, 13.
[25] Ex. 11.
[26] Test. of B. Wiebe;

**Scope and Severity Level**

Even if there was a deficiency, the Department failed to show that it warranted a Severity Level 3.

Minn. Stat. § 144A.10, subd. 16(d)(5), specifically authorizes determinations issued in connection with IIDR proceedings to include a finding that a citation's "[s]everity [is] not supported," and permits a recommendation to be made that a citation be "amended through a change in the severity assigned to the citation." There is no language in the statute limiting such situations only to immediate jeopardy or substandard quality of care severity levels. In addition, the federal regulations set forth in 42 C.F.R. § 488.331(a) require states to offer facilities an informal opportunity "to dispute survey findings." Thus, notwithstanding CMS's informal policy statements to the contrary in the State Operations Manual and Program Letter instructions, it appears that the Department's determination that the Resident suffered actual harm is a "survey finding" that may be disputed by the Facility in this IIDR.

The Interpretive Guidelines for skilled nursing facilities define level 3 "actual harm" deficiency determinations as follows:

> Level 3 is noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequence to the resident.[27]

The Tag may be assigned a Severity Level 2 if the noncompliance results in no more than minimal physical, mental or psychosocial discomfort to the resident and could compromise the resident's ability to maintain or reach her highest practicable level of well-being, as set forth in the resident's assessment, plan of care and provision of services.[28] Severity Level 2 is appropriate when the resident has no more than minimal discomfort and there is the potential to compromise the resident's ability to maintain or reach her highest practicable level of well being if interventions are not provided, but no actual harm.

The Department did not demonstrate that the harm rose to a severity level of 3. It failed to show that the Facility did not have a plan for pressure redistribution, that it failed to provide appropriate treatment or dressing changes, that the wound increased in size or failed to heal as anticipated, or that the resident experienced untreated pain, as directed by the Investigative Protocol. There was no evidence that the reoccurrence of the Stage II pressure ulcer compromised the Resident's ability to maintain her highest practicable physical, mental and psychosocial well-being. Pressure sores occurred occasionally and were treated. The presence of a pressure ulcer on September 17, 2009, did not affect the Resident's overall quality of life. She did not express that she

[27] Ex. C-2.
[28] Ex. C-2.

was in pain nor did the presence of the pressure ulcer impede her participation in the activities she enjoyed.

In this instance, the evidence shows that, if there was a delay in repositioning or changing the incontinent pad, it did not affect the Resident's ability to maintain or reach her highest practicable level of well-being, nor did the development of the pressure ulcer have a significant effect on her well-being.

The Scope of the deficiency was not challenged. The Department determined that the Scope of the violation was isolated, and that conclusion was consistent with the evidence presented.

Because of the lower severity level, the Psychosocial Outcome Severity Guide Level G is not appropriate in this case. Absent evidence of actual harm, with only the potential for more than minimal harm that is not immediate jeopardy, Level D is appropriate.

**Conclusion**

The Department failed to show that the Tag F314 was warranted or that the Resident suffered actual harm as a result of any deviation from the Resident's care plan. The deficiency should be removed from the Facility's record, or if the Department concludes that the deficiency should stand, the Severity Level should be reduced to 2.

**B. J. H.**